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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,077	04/28/2005	Kyung-Lim Lee	P27808	2398

7055 7590 01/25/2006

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EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,077	LEE ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 17-36 are pending and examined.

Applicant has canceled claims 1-16 and provided arguments for the patentability of claims 17-36 in the response filed 16 December 2005.

Applicant's arguments, see response, filed 16 December 2005, have been fully considered and are persuasive to the extent of the rejections under 35 USC §112 2nd, 35 USC §101 and 35 USC §102. Therefore, the rejection of claims 1-16 under 35 USC §101, claims 1-16 under 35 USC §112 second paragraph and the rejection of claims 1-16 under 35 USC §102, have been withdrawn. However, upon examination of the newly presented claims, a new ground(s) of rejection is made. Any rejection not specifically stated in this Office Action has been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

Examiner notes the reference to the foreign applications and withdraws any objection thereto.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 27, 31, 33 and 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating allergic diseases, does not reasonably provide enablement for the prevention of all allergic diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation.

The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1) the nature of the invention; the invention is directed to a composition and treating allergic diseases.

2) the breadth of the claims; the scope of the claims includes the prevention of all allergic diseases.

3) the predictability or unpredictability of the art; the ability of preventing all allergic diseases is not yet known in the art. The burden of enabling one skilled in the art to prevent all allergic diseases would be much greater than that of enabling the treatment of such diseases. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing allergic diseases. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing allergic diseases.

Specifically, it is highly unlikely, and the Office would require experimental evidence to support the contention that the claim specified actives could actually prevent all allergic diseases by simply administering, by any method, an amount of the claimed specified active agent. The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for preventing allergic diseases.

The term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not as of yet reasonably possible with most diseases/disorders, especially those having etiologies and pathophysiological

manifestations which are as complex/poorly understood as allergies, the specification is viewed as lacking an adequate enablement of where allergic diseases may be actually prevented.

4) the amount of direction or guidance presented; the specification does not provide any guidance in terms of preventing allergic diseases.

5) the presence or absence of working examples; no working examples are provided for preventing allergic diseases, for example in a patient, in the specification. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the preventative effects of the instant composition. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

6) the quantity of experimentation necessary; the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of preventing allergic diseases, and the lack of working examples regarding the activity as claimed, one skilled in the art

would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-6, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,933,323 to Noguchi et al. in view of US Patent No. 6,491,943 to Tsuji

et al. and further in view of the PDR document for omeprazole (cited to show status in the art).

Noguchi et al. teach a peptide possesses activity of inhibiting histamine release and IgE antibody production in the onset of type I-allergy which is effective in the prevention or therapy of type I-allergies such as bronchial asthma, urticaria and allergic rhinitis (in current claims 17-36; see abstract).

Tsuji et al. teach that catechins suppress histamine release (in current claims 20 and 26; see col 2 lines 14-16) and can treat allergies.

The PDR confirms that omeprazole is a proton pump inhibitor.

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. Specifically, the references combined show that proton pump inhibitors such as catechins, and likewise omeprazole, suppress or inhibit histamine release and that the inhibition of IgE dependent histamine release effectively treats allergic conditions such as asthma. One of ordinary skill in the art would have been motivated to combine the references because both are directed to the treatment of allergies comprising proton pump inhibitors. Moreover, combining agents which are known to be useful as treatments for allergies individually into a singe composition useful for the very same purpose is prima facie obvious. See In re Kerkhoven 205 USPQ 1069. Since it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same

purpose, the idea of combining omeprazole and catechin flows logically from their having been individually taught in the prior art.

Response to Arguments 35 USC § 112 1st Paragraph

Applicant's arguments filed 16 December 2005 have been fully considered with respect to the rejection over claims 1-16 and are persuasive to the extent that the claims have been canceled. Nonetheless, the rejection is maintained with respect to the new claims which include the "prevention" limitation.

Applicant's arguments filed 16 December 2005 have been fully considered but they are not persuasive. The term "prevent" or "prevention" in the claims is interpreted to mean that the action is prevented in all cases 100% of the time. As Applicant points out, complete prevention is not accomplished either in the prior art or in the instant case (wherein Example 2 at pages 12-13 of the present application it is described that the mortality rate of mice treated with the anaphylaxis-causing compound could be significantly decreased). A significant decrease in anaphylaxis does not amount to a complete prevention.

Response to Arguments 35 USC § 112 2nd Paragraph

Applicant's arguments filed 16 December 2005 have been fully considered with respect to the rejection over claims 1-16 and are persuasive to the extent that the claims have been canceled.

Response to Arguments 35 USC § 102

Applicant's arguments, see response, filed 16 December 2005, with respect to the rejection(s) of claim(s) 1-16 under 35 USC § 102 have been fully considered and are persuasive to the extent that claims 1-16 were canceled and the reference does not anticipate the newly recited claims. Therefore, the rejection has been withdrawn. However, upon examination of the new claims, a new ground(s) of rejection is made in view of US Patent No. 4,933,323 to Noguchi et al. in view of US Patent No. 6,491,943 to Tsuji et al.

US Patent No. 2002/0137785 to Kindness et al. is considered an equivalent to Tsuji et al. in that it teaches that the proton pump inhibitor omeprazole can be used to treat allergies.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20 January 2006
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Christopher S. F. Low

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